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Trace element status of women with contraceptive procedure ESSURE®

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Abstract

Background: ESSURE® (Bayer) is a permanent contraceptive procedure that uses a small implant inserted through the vagina and the cervix (by hysteroscopy) into the opening of each of the fallopian tube. The ESSURE® coils show a complex metal composition, including iron, nickel, chromium, titanium, silver, tin and platinum. The device has been linked to several serious health complications, including persistent pain, bleeding, allergic reactions possibly leading to removal surgery. Bayer stopped sales of ESSURE® in September 2018.

Objectives: The aims of this study were (1) to measure metal levels in urines, peritoneal fluid and fallopian tissues from women who underwent surgical removal of ESSURE® devices and (2) to evaluate the decrease of urinary toxic metals levels during follow-up of the patients.

Materials and Methods: This study was a sub-protocol of the single-center prospective cohort ABLIMCO study: Evaluation of symptom resolution after surgical removal of ESSURE® sterilization devices. Metal levels in urine and peritoneal fluid were compared to levels obtained from patients undergoing gynecological surgery for other indications. Metal levels in fallopian tissues close to ESSURE® device (fibrotic tissues) were compared to levels in non-fibrotic fallopian tissues. Toxic metals concentrations were determined by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) analysis in a PerkinElmer NexION 350.

Results: A total of 55 women with symptoms attributed to the device underwent removal surgery. The median delay between ESSURE® sterilization and removal surgery was 5.4 years. The preliminary results suggest higher levels of Cr, and to a lesser extent, of Ni in women who underwent surgical removal of ESSURE® devices.

Conclusions: The results of this study bring new aspects of the physiopathology of the symptoms associated with the ESSURE® device.